249/146US

REMARKS

With this response, claims 84, 86 and 105 have been amended.. Claims 1-42 were previously cancelled and claims 43-83 were withdrawn from consideration by the Examiner. Thus, the currently pending claims are claims 84-125.

As detailed below, claims 84 and 105 have been amended to enclose "w/v" in parentheses in order to be consistent throughout the claims. Claim 86 has been amended to correct a grammatical error. No new matter has been added.

Non-Art Based Rejections

Rejections Under 35 U.S.C. 112, Second Paragraph

In the Office Action, claims 84-125 were rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the use of "w/v" not enclosed in parentheses was alleged to be indefinite. In addition, the recitation of "about 0.005% to about 0.4% (w/v)" was alleged to be indefinite because "(w/v)" appeared only after the 0.4% and not after the 0.005%. Claims 86, 91, 93, 105 117 and 118 were rejected using the same reasoning. Applicants respectfully traverse these rejections.

"In rejecting a claim under the second paragraph of 35 U.S.C. 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims." Ex parte Wu, 10 U.S.P.Q 2d 2031 (B.P.A.I., 1989) citing In re Moore 439 F.2d 1232 (C.C.P.A., 1971). Applicants respectfully submit that the absence of parentheses around "w/v" does not render this well-established abbreviation indefinite, but that one skilled in the art would understand its meaning regardless of the presence or absence of parentheses. Likewise, Applicants respectfully submit that one skilled in the art would be able to ascertain the area set out by the phrase "about 0.005% to about 0.4% (w/v)." Further, Applicants contend that such usage is common in the

249/146US

scientific literature. Specifically, Applicants contend that one skilled in the art would readily recognize that (w/v) applies to both values in the phrase and so would not find the limitation indefinite. In the telephonic interview conducted September 9, 2004, with the undersigned Applicants' representative, the Examiner agreed that the above rejections should be withdrawn. Solely for the sake of consistency, and not to confer patentability, Applicant has amended claims 84 and 105 to enclose "w/v" in parentheses.

In the Office Action, claims 84, 87, 94-95, 113, 119 and 120 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "any combination thereof." Specifically, it was alleged in the Office Action that this resulted in an openended Markush group. Similarly, claim 93 was rejected under 35 U.S.C. 112, second paragraph, as indefinite for containing the phrase "or a combination thereof." Applicants respectfully traverse these rejections. Applicants respectfully submit that the recitation of a combination of elements within a Markush group does not render the claim indefinite and is in accordance with long-standing Patent Office practice and Federal Circuit jurisprudence. Applicants wish to respectfully draw attention to the recent Federal Circuit decision in Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 334 F.3d 1274 (Fed. Cir. 2003). In this case, the Federal Circuit approved of, and encouraged the use of, language similar to that in the present claims. Specifically the court stated "[i]f the patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim. See Meeting Held to Promote Uniform Practice In Chemical Divisions [28 J. Pat. & Trademark Off. Soc'y 849, 852 (1946)] (citing examples of qualifying language such as: 'and mixtures thereof' and 'at least one member of the group'." Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., 334 F.3d at 1281. Thus, Applicants submit that the language of the present claims is fully consistent with proper Markush practice and that the instant rejection should be withdrawn. During the telephonic interview with the Examiner on September 9, 2004, the Examiner agreed to withdraw the rejections.

In light of the telephonic interview of September 9, 2004 and the arguments presented above, Applicants respectfully request withdrawal of all outstanding rejections under 35 U.S.C. 112, second paragraph.

249/146US

Art Based Rejections

Applicants acknowledge that none of the currently pending claims stand rejected under either 35 U.S.C. 102 or 35 U.S.C. 103.

Obviousness Type Double Patenting

In the Office Action, claim 105 was provisionally rejected under the judicially created doctrine of obviousness double patenting. As detailed above, it is the Applicants' understanding that based on the telephonic interview of September 9, 2004, all other rejections are to be withdrawn leaving only the obviousness double patenting rejection. Under current Patent Office practice, when a provisional obviousness type double patenting rejection is made based on two applications, and the only remaining rejection is based on obviousness type double patenting, then the double patenting rejection should be withdrawn and the application allowed to issue. MPEP 804, Chart I-B. Thus, Applicants respectfully request withdrawal of this rejection.

249/146US

Conclusion

In light of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of all rejections set forth in the Office action of August 26, 2004. Further, Applicants respectfully submit that all claims presently under consideration are in a condition for allowance and requests issuance of a Notice of Allowance at the Examiner's earliest convenience.

Should the Examiner have any remaining questions regarding the subject invention or its patentability, Applicants encourage the Examiner to contact the undersigned to answer such questions or provide additional information.

Applicants believe that no fee is due in association with this response. If the Applicant is in error, the Commissioner is herewith authorized to charge any underpayment or credit any overpayment that may occur during the pendency of this application to Deposit Account No. 01-0535.

Respectfully submitted,

James E. Butler, Ph.D. Registration No. 40,931

AMYLIN PHARMACEUTICALS, INC. 9360 Towne Centre Drive San Diego, CA 92121 (858) 794-7330

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the above Response After Final in the application of Kolterman et al., Serial No. 09/889,330, filed December 27, 2001, is being submitted to the Commissioner for Patents, Washington DC by facsimile transmission to telephone number (703) 872-9306 on this 4th day of October, 2004.

.

Rened Zavata